AMENDED IN ASSEMBLY APRIL 14, 2004 AMENDED IN ASSEMBLY MARCH 31, 2004

CALIFORNIA LEGISLATURE—2003-04 REGULAR SESSION

ASSEMBLY BILL

No. 3044

Introduced by Assembly Member Yee

February 26, 2004

An act to add Article 5 (commencing with Section 125120) to Chapter 1 of Part 5 of Division 106 of the Health and Safety Code, *and to add Section 14110.53 to the Welfare and Institutions Code*, relating to prenatal testing.

LEGISLATIVE COUNSEL'S DIGEST

AB 3044, as amended, Yee. Prenatal ultrasounds.

The Hereditary Disorders Act requires the State Department of Health Services to establish regulations and standards for a hereditary disorders program, including with respect to clinical testing procedures for use in programs, facilities, and projects.

Existing law requires the department to administer a statewide program for the prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasounds.

This bill would require a person physician or sonographer, also known as an ultrasound technologist, who performs a prenatal ultrasound to detect congenital heart disease to substantiate that he or she meets meet the training and experience levels jointly developed by 3 nationally recognized organizations. The bill would prohibit a health facility or clinic, with the exception of a small and rural hospital, from permitting a person who does not meet these requirements from

AB 3044 — 2 —

5

7

8

9

performing a prenatal ultrasound to detect congenital heart disease unless certain conditions are met. The bill would require any person performing an ultrasound under these provisions to provide information to a pregnant woman regarding neonatal intensive care units in the area if a congenital abnormality is detected. The bill would make a violation of these prohibitions a misdemeanor. Because this bill would create a new crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Existing law provides for the Medi-Cal program, which is administered by the department and under which qualified low-income persons receive health care services.

This bill would provide that no reimbursement for the performance of a prenatal ultrasound shall be made under the Medi-Cal program if it is performed in a manner that violates the requirements of the bill.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes *no*.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the 2 following:
- 3 (a) The evaluation of the fetal heart is one of the more difficult 4 tasks for persons who perform prenatal, or fetal, ultrasounds.
 - (b) Congenital heart defects are one of the most common birth defects and associated with one of the highest mortality rates following birth.
 - (c) The incidence of congenital heart disease ranges from 8 to 10 incidents for every 1,000 births.
- 10 (c) One out of every 125 to 150 babies is born with a congenital 11 heart defect each year.
- 12 (d) Persons who perform prenatal ultrasounds to detect 13 congenital heart disease, including, but not limited to, physicians 14 and ultrasound technicians technologists, also known as

__ 3 __ AB 3044

sonographers, are not required to meet any specific training and experience levels.

- (e) Recommendations regarding how a routine prenatal ultrasound should be performed to detect congenital heart disease the content of a prenatal ultrasound examination and the competency of the physician interpreting, or performing and interpreting, the ultrasound and the sonographer to detect congenital heart defects have been developed jointly by the American Institute of Ultrasound in Medicine (AIUM), the American College of Radiology (ACR), and the American College of Obstetrics and Gynecology (ACOG) and are considered current standards of practice.
- (f) If these nationally recognized standards for performing prenatal—ultrasound that screens ultrasounds that screen for congenital heart defects were followed, prenatal detection rates of congenital heart disease and other fetal defects would significantly increase and result in improved outcomes for neonates and decreased costs to hospitals.
- SEC. 2. Article 5 (commencing with Section 125120) is added to Chapter 1 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 5. Prenatal Ultrasounds

- 125120. Any person—(a) Any physician who performs or interprets a prenatal ultrasound, also known as a fetal ultrasound, to screen for congenital heart disease in the state and a sonographer, shall substantiate that he or she meets meet the following training and experience levels with regard to the content of a prenatal ultrasound examination and the competency of the physician interpreting, or performing and interpreting, the ultrasound and the sonographer, which have been developed, as of January 1, 2004, and as revised or amended thereafter, jointly by the American Institute of Ultrasound in Medicine (AIUM), the American College of Radiology (ACR), and the American College of Obstetrics and Gynecology (ACOG):
- (a) The ultrasound shall be performed in "real time" rather than "still frame" for review by the physician, ultrasound technician, or both

AB 3044 — 4 —

(1) The ultrasound shall be performed and reviewed by the physician in "real time" or video clip rather than "still frame" or performed and recorded by the sonographer in "real time" or video clip rather than "still frame" for review by the physician for normal fetal heart function and rhythm and the presence of all four valves.

(b)

- (2) The ultrasound shall include a four chamber view to assess the size, position, axis, and symmetry of the heart and the great arteries.
- (e) A physician who performs the prenatal ultrasound shall substantiate that he or she has obtained 15 continuing medical education credits per year in antepartum or obstetrical ultrasound.
 - (d) An ultrasound technician
- (3) In the absence of the completion of a residency program, fellowship, or postgraduate training that includes the equivalent of at least three months of diagnostic ultrasound training in antepartum or obstetrical ultrasound, a physician who performs or interprets the prenatal ultrasound shall substantiate that he or she is involved with the performance, evaluation, and interpretation of a minimum of 150 fetal ultrasound procedures annually.
- (4) A sonographer who performs the prenatal ultrasound shall substantiate that he or she is certified by the national American Registry of Diagnostic Medical Sonographers (ARDMS) or the American Registry of Radiologic Technologists (ARRT) in obstetrical ultrasound and has obtained, or is in the process of obtaining, 30 continuing medical education credits over a three-year period in obstetrical ultrasound.
- (5) A newly graduated sonographer who is eligible for the ARDMS or ARRT examination for certification in obstetrical ultrasound may work under the direct supervision of a qualified physician. A newly graduated sonographer who has not taken the ARDMS or ARRT examination within two years of his or her graduation date may not perform a prenatal ultrasound pursuant to this paragraph.
- (6) Any person with a minimum of five years of work experience in this state as a sonographer shall be deemed in compliance with the requirements of this section.

__ 5 __ AB 3044

(b) For purposes of this article, a sonographer is also known as an ultrasound technologist.

125122. If a congenital abnormality is detected upon review of the prenatal ultrasound to screen for congenital heart disease, the performing physician or ultrasound technician shall provide information to the pregnant woman regarding the nearest and highest level neonatal intensive care unit in the geographical area for recommended followup prenatal care.

125123. A health facility or clinic may not permit a person who does not meet the requirements specified in Section 125120 to perform *or interpret* a prenatal ultrasound to detect congenital heart disease without the direct supervision of a qualified practitioner physician and unless the person demonstrates active participation in obtaining any continuing medical education eredits required under subdivision (e) or (d) of Section 125120. meeting the requirements of paragraphs (3), (4), or (5) of subdivision (a) of Section 125120.

125124. The department may adopt regulations to implement the requirements of this article.

125125. This article or any regulations adopted pursuant to this article shall not apply to any person who performs prenatal ultrasounds in a small and rural hospital, as defined in Section 124840, or a rural health clinic. For purposes of this subdivision, "rural health clinic" means a clinic that is located in an area that is not an urbanized area, as defined by the Bureau of the Census of the United States Department of Commerce, and in which there are insufficient numbers of needed health care practitioners, as determined by the Director of Health Services. is located more than 30 miles or 30 minutes driving distance from the city hall for any metropolitan area with a population of 150,000 or more.

125126. A violation of Any person who provides services in a manner that violates this article or any regulations adopted pursuant to this article shall be punishable as a misdemeanor. ineligible to receive reimbursement under the Medi-Cal program for those services as required under Section 14110.53 of the Welfare and Institutions Code.

125128. This article shall become operative on July 1, 2005. SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school

AB 3044 — 6 —

- 1 district will be incurred because this act creates a new crime or
- 2 infraction, eliminates a crime or infraction, or changes the penalty
- 3 for a crime or infraction, within the meaning of Section 17556 of
- 4 the Government Code, or changes the definition of a crime within
- 5 the meaning of Section 6 of Article XIII B of the California
- 6 Constitution.
- 7 SEC. 3. Section 14110.53 is added to the Welfare and 8 Institutions Code, to read:
- 9 14110.53. Commencing January 1, 2005, no reimbursement
- 10 for the performance of a prenatal ultrasound shall be made under
- 11 the Medi-Cal program if it is performed in a manner that violates
- 12 Article 5 (commencing with Section 125120) of Chapter 1 of Part
- 13 5 of Division 106 of the Health and Safety Code.